UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,134	04/11/2001	Leo J. Romanczyk JR.	5677-111	1617

7590 03/11/2003

Clifford Chance Rogers & Wells LLP
200 Park Avenue
New York, NY 10166-0153

EXAMINER
TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/833,134	Applicant(s) Romanczyk JR et al.
	Examiner Christopher Tate	Art Unit 1654

-- ***The MAILING DATE of this communication appears on the cover sheet with the correspondence address*** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *Feb 10, 2003* .

2a) X This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *1-29* is/are pending in the application.

4a) Of the above, claim(s) *1, 12-14, and 24-28* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) X Claim(s) *2-11, 15-23, and 29* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).
4) ☐ Interview Summary (PTO-413) Paper No(s).
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendment filed February 10, 2003 is acknowledged and has been entered.

Based upon the amendments made to claims 3-10 with respect to their now being directly or indirectly dependent from claim 2, these claims have been rejoined with the Group I invention.

Accordingly, claims 2-11, 15-23, and 29 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 112

Claim 19 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is rendered vague and indefinite by the phrase "fractionating the cocoa oil by ... chromatography" because, based upon the instant teachings, these chromatographic steps are not steps which would purify the oil, but instead appear to be analytical steps to assay the various components therein (see, e.g., pages 9-12 of the instant specification) and, therefore, the fractionation - chromatographic steps of claim 19 are outside the limitations of claim 15 which is a process of extracting a cocoa oil comprising phytosterols (and tocols) from cocoa hull, not a process of obtaining various fractions/constituents therefrom. Accordingly, it is again strongly suggested that claim 19 be canceled in response to this Office action.

Claim Rejections - 35 U.S.C. § 102

Claims 2-6, 9-11, and 29 are/stand rejected under 35 U.S.C. 102(b) as being anticipated by El-Saied et al. (Zeitschrift Fuer Erna., 1981) for the reasons set forth in the previous Office action which are restated below.

El-Saied et al. teach a fat (which reads upon an oil firstly because oil is naturally present in fat and, thus, fat is inherently comprised of oil; and secondly because fat is defined as "a solidified animal or plant oil" -Webster's II New Riverside University Dictionary, 1988) which contains phytosterols such as those instantly claimed obtained from cocoa shells via hexane extraction followed by evaporation of the hexane therefrom, and that, based upon chromatographic analyses, the cocoa shell fat was similar in composition to cocoa butter (see, e.g., pages 145-146, Materials and Methods; and pages 149-150 under the heading *Unsaponifiable matter composition*). Based upon the teachings of the instant disclosure (see, e.g., claim 16), the reference cocoa shell fat (oil) obtained by hexane extraction would inherently comprise tocols such as tocopherols and tocotrienols, since hexane is disclosed (see, e.g., claim 16) to be a suitable solvent for extracting both of the claimed ingredients (phytosterols and tocols) in producing the claimed cocoa shell oil.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 2-11 and 29 are/stand rejected under 35 U.S.C. 102(b) as being anticipated by Baskakova et al. (SU 1734748 - DWPI Abstract), or by Gavrilenko (Maslo-Zhir. Prom-st., 1977 - CAPLUS Abstract) for the reasons of record which are restated below.

Baskakova et al. teach a cocoa husk (hull) oil which is added to a cosmetic formulation (see abstract). The cocoa husk (hull) oil taught by Baskakova would inherently contain the phytosterols and tocols instantly claimed since these are natural constituents of cocoa husk (hull) oil.

Gavrilenko teaches an oil extracted from cocoa husk (hulls) which does not contain an extraction solvent (see abstract). The crude and refined cocoa husk oil taught by Gavrilenko would inherently contain the phytosterols and tocols instantly claimed since these are natural constituents of cocoa husk (hull) oil.

[With respect to the two cited references, please note that the patentability of a product does not depend on its method of production (see, e.g., MPEP 2113).]

Therefore, each of the cited references is deemed to anticipate the instant claims above.

Claim Rejections - 35 U.S.C. § 102/103

Claims 2-11, and 29 are/stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Warocquier-Clerout et al. (Int. J. Cosmetic Sci., 1992) for the reasons set forth in the previous Office action which are restated below.

Warocquier-Clerout et al. teach a lipid extract (which reads upon an oil extract) termed ICSB of cocoa shell butter which is extracted therefrom (the starting cocoa shell butter is obtained from cocoa shells) using solvents including petroleum spirits (which is synonymous to petroleum ether: see, e.g., The Condensed Chemical Dictionary, 10th ed., 1981). Based upon subsequent fractionation thereof using silica gel column chromatography, the ICSB lipid/oil extract was shown by Warocquier-Clerout et al. to contain various phytosterols (such as instantly claimed and disclosed) as well as tocols (such as instantly claimed and disclosed) - see, e.g., page 39, *Synopsis*; page 40, second full paragraph; and pages 41-42 in the Result section under the heading *Preparation and Fractionation of ICSB* including Table 1 and Figure 1).

Accordingly, the cited reference discloses a cocoa shell oil extract product which appears to be identical to the presently claimed cocoa shell oil extract product, since it was obtained using similar extraction solvent(s) and it was shown by Warocquier-Clerout et al. to contain the same ingredients as instantly claimed.

In the alternative, even if the claimed cocoa shell oil extract product is not identical to the referenced cocoa shell oil extract product with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced cocoa shell oil extract product is likely to inherently possess the same characteristics of the claimed cocoa shell oil extract product particularly in view of the similar characteristics which they have been shown to share. Thus, the oil extract product would have been obvious to those of ordinary skill in the art within the meaning of U.S.C. 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of clear and convincing evidence to the contrary.

Claim Rejections - 35 U.S.C. § 103

Claims 2-11, 15-23, and 29 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over El-Saied et al. (Zeitschrift Fuer Erna., 1981) and Warocquier-Clerout et al. (Int. J. Cosmetic Sci., 1992), in view of Mueller (J. Dairy Sci., 1959) and Alander et al. (WO 99/63031), and further in view of Newton (EP 0861600).

Also claimed is a method of extracting a cocoa oil comprising cocoa phytosterols from cocoa hulls comprising grinding the cocoa hulls, treating the ground cocoa hulls with a solvent which extracts phytosterols and tocols, removing the solvent, and recovering the oil.

The primary references are relied upon for the reasons set forth above.

Neither primary reference expressly teaches grinding the cocoa hulls prior to extraction nor using some of the extraction solvents instantly claimed.

Mueller beneficially teaches the extraction of components from cocoa shells, whereby the cocoa shells are first ground prior to solvent extraction (see, e.g., page 754). The grinding of herbal parts including nuts and seeds prior to extraction, such as beneficially disclosed by Mueller, is notoriously well known in the art to advantageously facilitate the release of desired components therefrom during such solvent extraction by maximizing surface exposure.

Alander et al. beneficially teach that oils extracted from various herbals such as cocoa butter contain phytosterols, tocopherols, and tocotrienols which can be effectively extracted using suitable extraction solvents including nonpolar solvents such as hexane and petroleum ether (see, e.g., page 1, third paragraph; pages 7-8; page 10, third full paragraph).

It would have been obvious to one of ordinary at the time the claimed invention was made to modify the extraction procedures taught by the primary references in making a cocoa shell oil extract product via grinding the cocoa shells prior to solvent extraction based upon the beneficial teachings of Muller with respect to this notoriously well known practice, and to use and/or substitute other suitable extraction solvents such as petroleum ether vs. hexane based upon the beneficially teachings provided by Alander et al. with respect to their equivalency as extraction solvents of cocoa butter which El-Saied et al. teaches is very similar to cocoa shell fat (thus, the skilled artisan would have a reasonable expectation of success in extracting cocoa shells using such equivalent solvents to obtained phytosterols - as well as tocols).

It would also have been obvious to the skilled artisan to utilize micronized cocoa hulls as a starting material because Newton beneficially discloses that micronizing is a commonly means of breaking the outer husks/hulls of cocoa beans during processing (see, e.g., col 5, lines 46-52), making them a readily available source. The adjustment of particular conventional working conditions (e.g., removing the solvent by vacuum distillation, further exposing such an oil extract to chromatographic techniques, using hulls from particular types of cocoa bean and/or from roasted or unroasted cocoa beans), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicants' arguments with respect to the art rejections above have been carefully considered but are not deemed to be persuasive of error in the rejection.

Applicants argue that the cocoa shell fat disclosed by El-Saied et al. does not read on oil and point to a dictionary definition of fat as being "a solid or semi-solid fat as distinguished from an oil". However, as discussed above, oil is naturally present within such fat and, thus, fat is inherently comprised of oil; and further, the Webster's II New Riverside University Dictionary defines fat as "a solidified animal or plant oil".

Applicant further argues that one cannot conclude from the limited teachings of the Baskakova et al. and Gavrilenko abstracts that the disclosed cocoa husk oil are the same as the claimed cocoa oil - because the fact that phytosterols and tocols may be present in cocoa husks does not mean they are necessarily present in cocoa oils obtained from cocoa husks. However, as discussed above, cocoa husk oil is deemed to inherently contain the phytosterols and tocols instantly claimed since these are natural constituents of cocoa husk (hull) oil - i.e., one of skill in the art would not reasonably conclude that the cocoa husk oils taught by Baskakova et al. and Gavrilenko do not contain these natural, inherent constituents.

Applicant also argues that the Warocquier-Clerout et al. reference suffers from the same deficiency as the El-Saied reference - i.e., it is directed to cocoa shell butter, not cocoa oil. However, the non-saponified lipid fraction obtained from cocoa shell butter, as taught by Warocquier-Clerout, is deemed to read upon cocoa shell oil since cocoa shell butter is naturally comprised of cocoa shell oil and, thus, such a non-saponified lipid fraction would inherently comprise the natural cocoa shell oil therein.

In addition, Applicants have argued and discussed references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicants' claimed invention fails to patentably distinguish over the state of the art represented by the references.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1651 is (703) 308-4242.

Christopher R. Tate
Primary Examiner, Group 1654

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 1, 12-14 and 24-28, drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1651 is (703) 308-4242.

Christopher R. Tate
Primary Examiner, Group 1654